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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/144,886	08/31/1998	JAMES D. MARKS	2307E-826US	5313

22798 7590 01/26/2004

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EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/144,886

Applicant(s)

MARKS ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 77 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,5,13-16 and 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-12,17-30,36-43 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed October 14, 2003 is acknowledged and has been entered. Claims 6-10, 17-21, 24-29, 36-40 and 77 have been amended. Claims 44-76 have been canceled. Claims 1, 3, 6-12, 17-30, 36-43 and 77 are under examination in the pending application. All rejections have been withdrawn in view of Applicants' amendment and/or comments, with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. This application contains claims 2, 4, 5, 13-16 and 31-35 are drawn to species nonelected with traverse in Paper No. 26. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. The rejection of claims 1, 3, 6-12, 17-30, 36-43 and now claim 77 under 35 U.S.C. § 102(a) as anticipated by Amersdorfer et al, 1997 is maintained. This rejection is maintained for essentially the same reasons as the rejection of claim under this statutory provision, as set forth in the last Office action.

Applicants' arguments filed December 13, 2001, have been fully considered but they are not deemed to be persuasive. Applicants have asserted that this reference is Applicants own work within the year before the application filing date

and that it cannot be used as prior art. Applicants state that upon a showing of otherwise allowable subject matter, Applicants will provide Katz declarations. It is noted that this rejection will be maintained until such declarations have been received.

The rejection is maintained for the reasons of record. Applicant's arguments filed October 14, 2003 have been fully considered but they are not persuasive. It is noted that rejection is maintained until properly filed Katz declarations have been received.

5. Claims 1, 3, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (Infection and Immunity, May 1997, 65/5:1626-1630).

Chen et al disclose an isolated single chain antibody and that these antibodies bind to BoNT/A and neutralizing antibodies against botulism poisoning (abstract; p. 1627; p. 1626; p. 1630).

The rejection is maintained for the reasons of record. Applicant's arguments filed October 14, 2003 have been fully considered but they are not persuasive.

Applicants have asserted that the Examiner has failed to identify any teaching in Chen et al establishing that the antibodies recited therein bind to epitopes bound by the present claimed antibodies. In addition, Applicants have asserted that Chen et al offers no teaching that any of the antibodies recited therein are neutralizing; and therefore that Chen fails to meet all of the limitations of the presently pending claims. However, the prior art discloses isolated single chain antibodies that bind epitopes in the variable heavy and variable light regions (see table 1 of Chen et al). The antibodies bind to epitopes specifically bound by antibodies expressed in a clone, the same or a similar variant (table 1). It is noted

that the properties recited in the wherein clause, “wherein said antibody binds to and neutralizes BoNT/A”, are viewed as inherent properties.

Since the Office does not have the facilities for examining and comparing applicants' antibodies with the antibodies of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the antibodies of the prior art does not possess the same material structural and functional characteristics of the claimed antibodies) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. No claims are allowed.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394 (1/27/04, 571-272-0860). The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909 (1/27/04, 571-272-0864). The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

January 20, 2004